

**Translation**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>09651</b>	<b>FOR FURTHER ACTION</b>	See Form PCT/IPEA/416																								
International application No. <b>PCT/JP2004/008471</b>	International filing date (day/month/year) <b>10.06.2004</b>	Priority date (day/month/year) <b>10.06.2003</b>																								
International Patent Classification (IPC) or national classification and IPC																										
Applicant <b>Dainippon Sumitomo Pharma Co., Ltd.</b>																										
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table><tr><td><input checked="" type="checkbox"/></td><td>Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/></td><td>Box No. II</td><td>Priority</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/></td><td>Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/></td><td>Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input type="checkbox"/></td><td>Box No. VIII</td><td>Certain observations on the international application</td></tr></table>			<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																								
<input type="checkbox"/>	Box No. II	Priority																								
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																								
<input type="checkbox"/>	Box No. IV	Lack of unity of invention																								
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																								
<input type="checkbox"/>	Box No. VI	Certain documents cited																								
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																								
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application																								
Date of submission of the demand	Date of completion of this report																									
Name and mailing address of the IPEA/JP	Authorized officer																									
Facsimile No.	Telephone No.																									

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/008471

Box No. I	Basis of the report
1.	<p>With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:</p> <p><input type="checkbox"/> international search (Rule 12.3 and 23.1(b))</p> <p><input type="checkbox"/> publication of the international application (Rule 12.4)</p> <p><input type="checkbox"/> international preliminary examination (Rule 55.2 and/or 55.3)</p> <p>2. With regard to the elements of the international application, this report is based on <i>(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)</i>:</p> <p><input type="checkbox"/> the international application as originally filed/furnished</p> <p><input checked="" type="checkbox"/> the description:</p> <p>pages <u>1-29</u> _____ as originally filed/furnished</p> <p>pages* _____ received by this Authority on _____</p> <p>pages* _____ received by this Authority on _____</p> <p><input checked="" type="checkbox"/> the claims:</p> <p>nos. <u>2-11, 15-23, 25</u> _____ as originally filed/furnished</p> <p>nos.* _____ as amended (together with any statement) under Article 19</p> <p>nos.* <u>1, 12, 13, 14, 24</u> _____ received by this Authority on <u>08.04.2005</u></p> <p>nos.* _____ received by this Authority on _____</p> <p><input checked="" type="checkbox"/> the drawings:</p> <p>sheets <u>fig. 1-4</u> _____ as originally filed/furnished</p> <p>sheets* _____ received by this Authority on _____</p> <p>sheets* _____ received by this Authority on _____</p> <p><input type="checkbox"/> a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.</p> <p>3. <input type="checkbox"/> The amendments have resulted in the cancellation of:</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p> <p>4. <input type="checkbox"/> This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).</p> <p><input type="checkbox"/> the description, pages _____</p> <p><input type="checkbox"/> the claims, nos. _____</p> <p><input type="checkbox"/> the drawings, sheets/figs _____</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>): _____</p> <p><input type="checkbox"/> any table(s) related to sequence listing (<i>specify</i>): _____</p>

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/008471

## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 22, 23

because:

☒ the said international application, or the said claims Nos. 22, 23

relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions that are set forth in claims 22 and 23 are commercial methods and advertisement methods, and as such correspond to methods for carrying out business activities. Thus, claims 22 and 23 relate to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Rule 67.1(iii).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 22, 23

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/008471

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-11, 24, 25	YES
	Claims	12-21	NO
Inventive step (IS)	Claims	1-11	YES
	Claims	12-21, 24, 25	NO
Industrial applicability (IA)	Claims	1-21, 24-25	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
Document 1: CHEST, Vol. 123, No. 5, May 2003, pp. 1375 to 1378			
Claims 12 to 21, 24 and 25			
<p>Document 1 presents a method wherein D-dimer specific monoclonal antibodies are employed in order to measure the level of D-dimers in a patient who presents with an acute aortic dissection.</p>			
<p>The reagents that are set forth in claims 12 to 21 can be considered to include antibodies that are capable of recognizing the appropriate D-dimers for identifying the illnesses that are set forth in said claims. However, as substances, the D-dimer specific monoclonal antibodies that are presented in document 1 are the same as the antibodies that are set forth in claims 12 to 21, and said D-dimer specific monoclonal antibodies can be considered to have a configuration that is suitable for identifying the illnesses that are set forth in claims 12 to 21.</p>			
<p>Therefore, the inventions that are set forth in claims 12 to 21 lack novelty (refer to section 5.23 of the PCT International Search and Preliminary Examination Guidelines).</p>			

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/008471

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

In addition, it would have been natural for a person skilled in the art to employ antibodies in order to configure reagents.

Claims 1 to 11

The feature of measuring the level of D-dimers in the blood of a patient who presents with either an acute aortic dissection or an acute myocardial infarction and then determining that said patient may have suffered an acute aortic dissection in cases when the measured D-dimer concentration exceeds a pre-set cut-off value for the level of D-dimers in the blood, and the feature of measuring the level of the D-dimers in the blood and then determining whether or not a Stanford A-type acute aortic dissection, a Stanford B-type acute aortic dissection or an acute myocardial infarction has occurred based on the concentration of the D-dimers in the blood are not disclosed in any of the documents that are cited in the international search report, and would not have been obvious to a person skilled in the art.